

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

REBECCA and CHRISTOPHER HULL,
Plaintiffs,

Case No. _____

vs.
BAYER CORPORATION, BAYER HEALTHCARE
PHARMACEUTICALS INC., BAYER HEALTHCARE,
LLC, and DOES ONE through ONE HUNDRED, inclusive,
Defendants.

**COMPLAINT FOR DAMAGES AND
DEMAND FOR JURY TRIAL**

DEMAND FOR JURY TRIAL

NOW COME PLAINTIFFS, by and through the undersigned counsel, and for their Complaint hereby aver and state as follows:

NATURE OF THE ACTION

1. This is an action brought by Plaintiffs for damages associated with ingestion of the pharmaceutical drug Yaz, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.
2. As a result of the ingestion of Yaz, Plaintiff suffered injuries to her person including, but not limited to, cardio-pulmonary arrest and stroke on June 10, 2008.

THE PARTIES

3. Plaintiff Rebecca Hull, (herein "Plaintiff"), currently lives and at all times relevant to this complaint has lived in the city of Bedford, Tarrant County, Texas.
4. Plaintiff is married to Christopher Hull who also lives in the city of Bedford, Tarrant County, Texas.
5. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.
6. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.
7. Defendant BAYER HEALTHCARE LLC, is, and at all times relevant was, a limited liability

corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburgh, PA 15205.

8. At all times relevant, Defendant BAYER HEALTHCARE LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.
9. Defendant BAYER HEALTHCARE LLC is wholly owned by Defendant BAYER CORPORATION.
10. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.
11. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.
12. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.
13. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045- 1000.
14. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.
15. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.
16. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of approved

New Drug Application (“NDA”) for Yaz.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.
18. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.
19. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.
20. Defendant BAYER SCHERING PHARMA AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.
21. Defendant BAYER SCHERING PHARMA AG is a corporate successor to Schering AG.
22. SCHERING AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.
23. Defendant BAYER SCHERING PHARMA AG’S headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.
24. At all times relevant, Defendant BAYER SCHERING PHARMA AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.
25. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, Yaz.
26. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.
27. Defendant BAYER AG is the third largest pharmaceutical company in the world. Defendant BAYER AG is the parent/holding company of all other named Defendants. Defendant BAYER

AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

28. At all times relevant, Defendant BAYER AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, YAZ.
29. Defendants John Doe Manufacturers (DOES 1-50, fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yaz into interstate commerce, including the Northern District of Texas and derived substantial revenue from these activities.
30. Defendants John Doe Distributors (DOES 51-100, fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, marketing, and/or placing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Yaz into interstate commerce, including the Northern District of Texas and derived substantial revenue from these activities.
31. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., Bayer Schering Pharma AG, Bayer AG, John Doe Manufacturers and Distributors DOES 1-100 shall be referred to herein individually by name or jointly as "Defendants."
32. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptive, Yaz.
33. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents,

representatives and any and all other persons acting on their behalf.

34. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

35. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.
36. Venue is proper in the Northern District of Texas pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events or omissions giving rise to the claims occurred within this district, including, but not limited to, the development, design, licensing, labeling, manufacturing, advertising and/or marketing of the defective drug, as well as Defendants' fraud and conspiracy to actively conceal and/or misrepresent information concerning the safety and efficacy of Yaz with the intention and specific desire to mislead the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff.
37. Defendants expected or should have expected that their business activities could or would have consequences within the State of Texas, as well as throughout the United States.

FACTS

Yasmin and YAZ Background

38. Yasmin, (a predecessor to Yaz), known generically as drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC containing the hormones estrogen and progestin.
39. The estrogen is ethinyl estradiol and the progestin is drospirenone, (3 mg of drospirenone and 0.03 mg of ethinyl estradiol per tablet).
40. Combination birth control pills are referred to as combined hormonal oral contraceptives.
41. Yasmin was approved by the FDA in April, 2001.
42. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC, and began marketing an almost identical drug, Yaz (which contains 3 mg of drospirenone and 0.02 mg of ethinyl estradiol per tablet).
43. The difference between Yaz/Yasmin and other birth control pills on the market is that

drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

44. Shortly after the introduction of combined oral contraceptives in the 1960s, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks and strokes than women not using the pill.
45. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks and strokes.
46. During this time, new progestins were being developed, which became known as “second generation” progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks and strokes and were considered safer for women.
47. During the 1990s, new “third generation” progestins were developed. Unfortunately, these “third generation” progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or “DVT”) and lungs (pulmonary embolism or “PE”) . As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.
48. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.
49. However, drospirenone is a new type of progestin and is considered a “fourth generation” progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name, Ocella.
50. Since drospirenone in birth control is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.
51. YAZ/YASMIN’s use of drospirenone, a diuretic, creates unique risks for compared to other oral contraceptives and is known to cause medical problems, including severe heart arrhythmias.
52. Upon information and belief, Defendants knew or should have known about the correlation between the use of YASMIN and YAZ and significantly increased risk of severe heart

arrhythmias.

53. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.
54. Hyperkalemia can cause various medical complications, including heart rhythm disturbances, such as extrasystoles, pauses or bradycardia. If left untreated, hyperkalemia can be fatal.
55. Drospirenone increases the risk of and permits blood clots to form, including deep vein thrombosis. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.
56. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form, including deep vein thrombosis. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.
57. During the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

Defendants' Over-Promotion, Fraud and Failures Regarding Yasmin and Yaz

58. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.
59. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.
60. Yet, despite the wealth of scientific information available, Defendant ignored the correlation between the use of YASMIN and YAZ and significantly increased risk of severe heart arrhythmias and still promoted, sold, advertised, and marketed the use of YAZ/YASMIN without sufficient warnings.
61. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of Yaz and/or its predecessor Yasmin, and minimize serious risks associated with the drug.
62. Indeed, the FDA felt Defendants' over-promotion of Yaz was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements.

63. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.
64. Defendants ignored the correlation between the use of Yasmin and Yaz and increased thrombosis formation despite the wealth of scientific information available.
65. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin and Yaz and strokes and still promoted, sold, advertised, and marketed the use of Yasmin and Yaz.
66. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Yasmin and Yaz had been tested and was found to be safe and/or effective for its indicated use.
67. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense, purchase and use Yasmin and Yaz despite the risks, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.
68. Defendants knew and were aware or should have been aware that Yasmin and Yaz had not been sufficiently tested, was defective in its design and testing, and/or lacked adequate and/or sufficient warnings.
69. Defendants knew or should have known that Yasmin and Yaz had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.
70. In representations to Plaintiff, her healthcare providers, the public and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:
 - A. That Yasmin/Yaz is not as safe as other available contraceptives;
 - B. That the risks of adverse events with Yasmin/Yaz (drospirenone and ethinyl estradiol) were higher than those of other available contraceptives;
 - C. That the risks of adverse events with Yasmin/Yaz were not adequately tested and/or known by Defendants;
 - D. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not

limited to, stress, pulmonary embolisms, heart attacks, gallbladder complications, as well as other severe and personal injuries, physical pain, and mental anguish;

E. That patients needed to be monitored more regularly than normal while using Yasmin/Yaz; and/or

F. That Yasmin/Yaz was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

71. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Yasmin and Yaz.
72. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Yasmin and Yaz, including Plaintiff.
73. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and Yaz with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin and Yaz as a contraceptive.
74. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and Yaz in their labeling, advertising, product inserts, promotional material or other marketing efforts.
75. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.
76. Defendants knew that Plaintiff, her healthcare providers, the public, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin and Yaz, as set forth herein.
77. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin and Yaz.
78. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of Yaz in a timely manner, yet they failed to provide such warning.

FACTS REGARDING PLAINTIFF REBECCA HULL

79. Plaintiff Rebecca Hull was prescribed Yaz by her health care provider in approximately July 2006.
80. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Yaz to her detriment.
81. As a result of using Defendants' product Yaz, Plaintiff sustained serious side effects including, but not limited to, a stroke in June of 2008, ongoing physical pain, diminished cognition, mental anguish, diminished enjoyment of life, significant lifestyle changes, permanent scarring, medical, health, incidental and related expenses, medical monitoring and/or medications, and the fear of developing additional health consequences.
82. Plaintiff did not discover, nor did she have any reason to discover that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, until at least June of 2008.

CAUSES OF ACTION

COUNT I

Strict Liability

83. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.
84. At the time of Plaintiff's injury, Defendants' pharmaceutical, Yaz, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.
85. The Yaz used by Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants.
86. Plaintiff did not misuse or materially alter the Yaz.
87. Plaintiff was using YAZ in the manner for which it was intended and/or in a reasonably foreseeable manner.
88. Plaintiff was not aware of and reasonably could not have discovered the dangerous nature of YAZ.
89. Defendants are strictly liable for Plaintiff's injury in the following ways:
- A. The pharmaceutical Yaz was designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

- B. Defendants failed to properly market, design, manufacture, distribute, supply and sell Yaz;
- C. Defendants failed to warn and/or place adequate warnings and instructions on Yaz.

Defendants' failure to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects of the drug;

- D. Defendants failed to adequately test Yaz. Defendants' failure to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, severe heart arrhythmias, and other serious and life threatening side effects;
- E. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of Yaz;
- F. Defendants' failure to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug;
- G. Defendants' encouragement of misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to maximize profit from sales; and
- H. A feasible alternative design existed that was capable of preventing Plaintiff's injury.

90. Defendants' actions and omissions were the direct and proximate cause of Plaintiff's injury.

91. As a result of the foregoing acts and omissions, Plaintiff suffered serious and life-threatening side effects including, but not limited to, severe stroke, as well as other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, and the need for ongoing medical treatment, monitoring and/or medications.

92. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT II

Fraudulent Concealment

93. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.

94. Prior to Plaintiff's use of Yaz and during the period in which Plaintiff actually used Yaz, Defendants fraudulently suppressed material information regarding the safety and efficacy of Yaz, including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pill using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Yaz strong.
95. Defendants knew or should have known that Yaz was being used to treat menstrual symptoms including but not limited to, heavy menstrual bleeding, painful menstrual periods, irregular menstrual periods, and premenstrual dysphoric disorder.
96. Defendants fraudulently concealed safety issues with Yaz in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use Yaz.
97. At the time Defendants concealed the fact that Yaz was not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the Healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Yaz.
98. Plaintiff and the Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of Yaz.
99. As a direct and proximate result of Defendants' malicious and or intentional concealment of material life altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiff's injuries.
100. It is unconscionable and outrageous that Defendants would risk the lives of consumers. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.
101. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of Yaz as described herein. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the

Healthcare community and the general public.

COUNT III

Breach Of Implied Warranty Of Merchantability

102. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.
103. At the time Defendants marketed, distributed and sold Yaz to Plaintiff, Defendants knew of the intended, reasonably foreseeable and/or ordinary use of the drug and warranted that Yaz was merchantable, safe and fit for such use.
104. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.
105. Yaz was not merchantable or safe or fit for its intended, reasonably foreseeable and/or ordinary purpose, because it has a propensity to lead to the serious personal injuries described in this complaint.
106. Plaintiff, in ingesting Yasmin, reasonably relied upon the skill and judgment of Defendants as to whether Yaz was of merchantable quality and safe for its intended, reasonably foreseeable and/or ordinary use.
107. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injury.
108. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT IV

Breach Of Implied Warranty Of Fitness For A Particular Purpose

109. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges on information and belief as follows.
110. Defendants sold Yaz with an implied warranty that it was fit for the particular purposes of safe birth control, and to provide other benefits, such as reduced bloating, reduced mood swings, improved complexion, and reduced severity of symptoms accompanying menstruation.

111. Members of the consuming public, including Plaintiff, were intended third party beneficiaries of the warranty.
112. Yaz was not fit for the particular purpose of a safe birth control pill and other known benefits without serious risk of personal injury, which risk is much higher than other birth control pills.
113. Plaintiff reasonably relied on Defendants' representations that Yaz was safe and effective for use as a birth control method and other known uses.
114. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiff's injury.
115. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT V

Negligent Failure To Warn

116. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.
117. Before Plaintiff used Yaz, and during the period in which she used it, Defendants knew or had reason to know that Yaz was dangerous and created an unreasonable risk of bodily harm to consumers.
118. Defendants had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made Yaz likely to be dangerous.¹⁰⁶ Despite the fact that Defendants knew or had reason to know that Yaz was dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made Yaz likely to be dangerous.
119. The Plaintiff's injury was a direct and proximate result of Defendants' failure to warn of the dangers of Yaz.
120. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of

the safety and efficacy problems and suppressed this knowledge from the general public.

Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VI

Negligence

121. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.
122. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of Yaz, including a duty to assure that the product did not cause unreasonable, dangerous side effects to users.
123. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of Yaz in that Defendants knew or should have known that the drug created a high risk of unreasonable harm.
124. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of Yaz in that, among other things, they:
 - A. Failed to use due care in designing and manufacturing Yaz so as to avoid the aforementioned risks to individuals;
 - B. Failed to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;
 - C. Failed to provide adequate training and instruction to medical care providers for appropriate use of Yaz;
 - D. Encouraged the drug's misuse and overuse while failing to disclose the severity of the side effects of the drug to the medical, pharmaceutical and scientific communities and users, including plaintiff, in order to maximize profit from sales.
 - E. Placed an unsafe product into the stream of commerce; and
 - F. Were otherwise careless or negligent.
125. Despite the fact that Defendants knew or should have known that Yaz caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market Yaz to consumers, including the medical community

and Plaintiff.

126. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VII

Negligent Misrepresentation

127. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows. Prior to Plaintiff first using Yaz and during the period in which she used Yaz, Defendants misrepresented that Yaz was a safe and effective as a means of birth control and for other known uses. Defendants also failed to disclose material facts regarding the safety and efficacy of Yaz, including information regarding increased adverse events, harmful side effects, and results of clinical studies showing that use of the medication could be life threatening.
128. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.
129. Defendants knew or should have known, based on their prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with Yaz, that their representations regarding Yaz were false, and that they had a duty to disclose the dangers of Yaz.
130. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing Yaz.
131. Plaintiff justifiably relied on Defendants' representations and nondisclosures by purchasing and using Yaz.
132. Defendants' misrepresentations and omissions regarding the safety and efficacy of Yaz was the direct and proximate cause of Plaintiff's injuries.
133. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with

knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VIII

Breach Of Express Warranty

134. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.
135. Through aggressive marketing and advertising campaigns, Defendants expressly warranted that Yaz was safe and effective to members of the consuming public, including Plaintiff.
136. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty. Defendants marketed, promoted and sold Yaz as a safe for birth control and other known uses.
137. Yaz does not conform to these express representations because Yaz is not safe and has serious side effects, including death.
138. Defendants breached their express warranty in one or more of the following ways:
- A. Yaz, as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
 - B. Defendants failed to warn and/or place adequate warnings and instructions on Yaz;
 - C. Defendants failed to adequately test Yaz; and
 - D. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from Yaz.
139. Plaintiff reasonably relied upon Defendants' warranty that Yaz was safe and effective when she purchased and used the medication.
140. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.
141. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general

public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT IX

Fraudulent Misrepresentation

142. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.
143. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Yaz, owed a duty not to deceive the Plaintiff, her health care providers and the public regarding the character, safety, quality and/or effectiveness of their drug.
144. The duty not to deceive is distinct from than the duty to warn.
145. Since the drug's approval in April of 2001, and on multiple occasions to the present date, Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality and/or effectiveness, including, but not limited to, the public ad campaigns which were the subject of the FDA's 2003, 2008 and 2009 warnings.
146. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.
147. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding Yaz.
148. Defendants acted with deliberate intent to deceive and mislead Plaintiff, her medical providers, and the public.
149. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.
150. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered the harm described herein.
151. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNTS X-XI

Civil Conspiracy And Commercial Bribery

152. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.
153. Defendants committed civil conspiracy, commercial bribery and conspiracy to commit commercial bribery in that fiduciaries of Defendants knowingly and/or intentionally offered, conferred, or agreed to confer benefits, gifts, and/or gratuities or conspired to do the same upon physicians, pharmacists, and insurance companies for the purpose of enticing these entities to use the drugs Yaz, and to convince their patients and others of the safety and effectiveness of Yaz.

COUNT XII

Loss Of Consortium

154. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.
155. Plaintiff Christopher Hull brings this cause of action for Loss of Consortium.
156. By reasons of the injuries sustained by Rebecca Hull, Plaintiff Christopher Hull has been and will continue to be deprived of consortium, society, comfort, protection, and service, thereby causing and continuing to cause grief, sorrow, mental anguish, emotional distress, pain and suffering.

COUNT XIII

Punitive Damages

157. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.
158. Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public, thereby entitling her to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants, jointly and severally, as follows:

- A. For an award of compensatory damages, including damages against Defendants and each of them for personal injuries, medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of \$75,000;
- B. For an award of punitive or exemplary damages against Defendants and each of them in excess of \$75,000;
- C. For reasonable attorneys' fees and costs;
- D. For pre-judgment interest; and
- E. For such further and other relief the court deems just, equitable, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: December 29, 2009

Respectfully submitted,

By: /s/ Shezad Malik
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